SUMMARY

Inspection of this class II medical device manufacturer was conducted as a routine FY11 work plan assignment (Facts #1249426). This was a level II QSIT inspection performed per CP 7382.845. This inspection was one of three roughly concurrent inspections of Pittsburgh area Medrad, Inc. manufacturing sites, each of which shares a common quality management system and is separately registered. Establishment Inspection Report for the Indianola plant serves as the lead EIR for this series of inspections. The previous FDA inspection of this particular facility (The Heilman Center) was conducted in mid 2008 and was classified NAI.

The current inspection revealed no significant control problems for this site, which is Medrad's electro-mechanical assembly plant and service depot. No FDA 483 was issued.

ADMINISTRATIVE DATA

Inspected firm:	Medrad, Inc.
Location:	625 Alpha Dr Pittsburgh, PA 15238-2819
Phone:	412-767-2400
FAX:	412-767-8899
Mailing address:	100 Global View Drive Attn: Corporate Compliance Warrendale, PA 15086
Dates of inspection:	1/20/2011, 1/21/2011, 1/25/2011, 1/26/2011, 1/27/2011
Days in the facility:	5
Participants:	James M. O'Donnell, Investigator

This inspection was pre-announced uneventfully. Because there were several local Medrad sites under concurrent inspection, the inspection days were not continuous and reporting for each site, including this one, was delayed pending preparation of the lead EIR. Several issues relating to products manufactured at this site were discussed at the Indianola site, where design cognizance resides.

HISTORY / INTERSTATE COMMERCE / JURISDICTION

Medrad history, I/S commerce and jurisdictional issues have been described in previous EIRs as well as the January 2011 EIR for the Indianola site. The O'Hara Township location (Heilman Center) is engaged in manufacture of all Medrad's electro-mechanical products including CT, MR

and CV injectors, monitors and infusion pumps. Site also performs servicing / repair of the same products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Mike Kochis, as Plant Manager of this site, is reportedly responsible for the daily operations at the facility. Mr. Sam Liang, as President and CEO of Medrad, Inc., is ultimately responsible for operations. Design cognizance for products and product line business management functions reside at the Indianola site. Overall corporate governance and major decisions are reportedly based at the Warrendale, PA HQ facility were executive management is based.

Upon arrival I presented credentials and a Notice of Inspection to Mr. Kochis. Ms. Julia Mitrchell and Mr. Larry Kopyta were present throughout the inspection and facilitated information retrieval and responses to my inquiries. Other individuals particcpating substantially included Mr. Matt Boyle, EMM Quality Plant Manager; Mr. Joe Kridgen, Director, Operations Quality; George Papcun, QA Engineer; Mike Emeloff, Site Quality Engineer; Brent Clarke, Product Analysis Group (910); Andy Deutsch, Product Manager NPD; and Pete Panagis, Sr. Engineering Manager NPD.

MANUFACTURING/DESIGN OPERATIONS

This site is engaged in higher order manual assembly and repair of electromechanical devices, and functional testing (largely automated) of same. Products produced include injectors, physiological monitors and pumps. Some repair and servicing (only) activities are performed on regulated products at this site, including some third party products.

INSPECTION COVERAGE / FINDINGS

This level II QSIT inspection included coverage of Management Controls activities relating to electro-mechanical (EM) product, CAPA activities associated with electro-mechanical products and Production and Process Controls applied to operations at this site. I reviewed elements of management review activities covering EM devices and observed no deficiencies. I reviewed in considerable detail the firm's trending and analysis activities covering internal non-conformances, complaints and service actions. I observed no systemic deficiencies with respect to firm's trending and analysis of quality system information for EM products as required by the QSR.

I reviewed complaint handling activities for E-M products, and while no systemic deficiencies were observed, I discussed with the firm my observation that numerous repair actions for non-functional XDS (extravasation detection) system sensor elements were being reported with only 1 instance of a documented investigation of the cause of the failure. I expressed that it was not clear to me that each of the failed sensor problems documented in service notifications was the same failure mode, and that it seemed they were mischaracterizing these events as "routine servicing" as opposed to complaints. I explained that routine servicing refers to regularly scheduled, anticipated actions and not unexpected functional failures. Generally speaking, however, I observed that the

firm does an appropriate job of investigating complaints, especially those of higher potential risk significance.

I reviewed specific functional test procedures applied to Avanta injectors and found no problems with respect to the adequacy of the controls applied including available procedures, instrumentation issues or qualification of ATE.

I reviewed acceptance activities and management for acceptance requirements for selected materials and observed no systemic problems.

I discussed with the firm issues relating to a field actions conducted on fielded Avanta fluid management systems, including software modifications and disposable product withdrawals conducted as part of the firm's roll-out of enhanced disposables and modified purge procedures for this platform. These issues were a major discussion topic and included potential required reporting under part 806. These issues are addressed in the EIR for the Indianola facility, where design cognizance and major program decision making for various platforms is based.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No significant objectionable conditions were observed, no FDA 483 was issued. I advised the firm that additional review of recent Avanta field actions may occur during subsequent review of reporting for this site and the Indianola location.

REFUSALS

None.

GENERAL DISCUSSION WITH MANAGEMENT

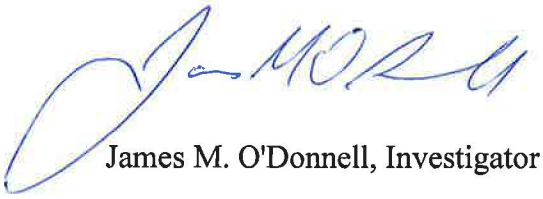
Final discussions were held at the Indianola site. The only issue discussed that specifically related to activities occurring at this site (Heilman Center) was my comments on potential failure to investigate XDS system sensor functional failures, or to document relationship of individual events to an earlier documented investigation. This concern was expressed in a more general way relating to the firm's potential misuse or over-use of a "routine service" characterization to exclude a requirement to investigate functional failures. To the extent I observed these concerns related to issues of lower risk significance and was not systemic, I chose to not cite the firm for this issue at close-out. Firm was advised the inspection of this location was officially closed during close-out meeting at the Indianola facility on 2/3/11.

SAMPLES COLLECTED

None

ATTACHMENTS

1) FDA 482 Notice of Inspection



James M. O'Donnell, Investigator